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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,312	02/15/2002	John McKenzie	271/094	3792

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/25/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,312

Applicant(s)

MCKENZIE ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 13-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a catheter apparatus, classified in class 623, subclass 1.23.
- II. Claims 13-23, drawn to a method of performing surgery, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. The method of Group II does not require the filter to be a mesh of varying porosity.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

If applicant elects Group I, this application contains claims directed to the following patentably distinct species of the claimed invention:

- a) Catheter shaft positioned external to expandable conduit
- b) Catheter shaft positioned internal to expandable conduit

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If applicant elects Group II, this application contains claims directed to the following patentably distinct species of the claimed invention:

- a) Elongate member is a catheter
- b) Elongate member is a guidewire

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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During a telephone conversation with John Kappos on 9/18/03 a provisional election was made with traverse to prosecute the invention of Group I, species (b), claims 1-10 and 12.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 11 and 13-23 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

1. The Information Disclosure Statement filed 2/15/02 has been entered as Paper No. 6. A copy of the Katz et al. reference under "Non Patent Literature" is not yet available to the examiner for consideration. This reference will be considered in the next office action.

Interference

2. Claims 1-12 of this application have been copied from U.S. Patent No. 6,254,563 for the purpose of an interference.

Applicant has failed to specifically apply each limitation or element of each of the copied claim(s) to the disclosure of the application.

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In response to this office action, applicant must specifically apply each limitation or element of each of the copied claim(s) to the disclosure of the application. See 37 CFR 1.607(a)(5).

3. Because the effective filing date of the application is more than 3 months after the effective filing date of the patent (6,254,563), 37 CFR 1.608(b) requires that the applicant must file (1) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is prima facie entitled to a judgment relative to the patentee, and (2) an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment.

4. Because applicant is claiming the same invention as a patent which has an earlier effective United States filing date and there is not a statutory bar against the application, and the applicant has not submitted the items required by 37 CFR 1.608(a) and (b), as appropriate, the application can be rejected under 35 U.S.C. 102(e)/103. The patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note, however, 35 U.S.C. 135(b) and MPEP § 2307.02. An affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference number "220"

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from Figure 5 is not mentioned in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word "said" on line 2 is legal phraseology that needs to be removed.

7. The disclosure is objected to because of the following informalities:

- a) On page 22, line 13, "cannula 210" should be changed to either --cannula 205-- or --cannula 230-- because "210" is used to designate "distal end".
- b) A brief description of Figure 24B is missing.

Appropriate correction is required.

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8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

- a) Claim 1: “filter mesh material of varying porosity”
- b) Claim 2: “upstream sealing member comprises an inflatable toroidal balloon”
- c) Claim 3: “a perfusion lumen within said catheter shaft in fluid communication with a space exterior to said expandable conduit”
- d) Claim 4: “at least one longitudinal support member attached to a wall of said expandable conduit”
- e) Claim 5: “an end wall of porous fabric across said downstream end of said expandable conduit”
- f) Claim 6: “an occlusion member for selectively occluding said expandable member”
- g) Claim 7: “an infusion lumen within said catheter shaft having an infusion port upstream of said occlusion member”
- h) Claim 8: “a second perfusion lumen within said catheter shaft”
- i) Claim 10: “said occlusion member is an inflatable occlusion balloon”

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Independent claim 1 contains a limitation (“filter mesh material of varying porosity”) that was not previously disclosed as part of the invention. Therefore, claims 1-12 do not receive benefit of the earlier filing dates of the parent applications. The effective filing date of claims 1-12 is the date they were filed, 2/15/02.

11. Claims 1-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Macoviak et al. (USPN 6,139,517, as cited in applicant’s IDS).

Macoviak et al. discloses a catheter apparatus for use in a body with all the elements of claim 1. See columns 3-4, lines 53-32 and figures for a catheter shaft and an expandable conduit defined by a filter mesh material (column 17, lines 25-26) of varying porosity (column 17, lines 54-56) mounted on the catheter shaft. The expandable conduit has an upstream end and a downstream end (column 3, lines 53-55). The expandable conduit has a collapsed position in which the expandable conduit is collapsed toward the catheter shaft and an expanded position in which the upstream end of the expandable conduit is open to fluid flow (see figures). An upstream sealing member at the upstream end of the expandable conduit creates a seal between the upstream end of the expandable conduit and an internal wall of the body passage (columns 5-6, lines 66-3).

Claim 2, see column 4, lines 8-10 for inflatable toroidal balloon.

Claim 3, see column 7, lines 49-50 for a perfusion lumen (122).

Claim 4, see column 6, lines 22-25 for longitudinal support member (136).

Claim 5, see column 17, lines 26-29 for end wall of porous fabric.

Claims 6, 7 and 10, see claims 8, 9 and 29, of Macoviak et al., respectively.

Claim 8, see column 12, lines 28-29 for second perfusion lumen.

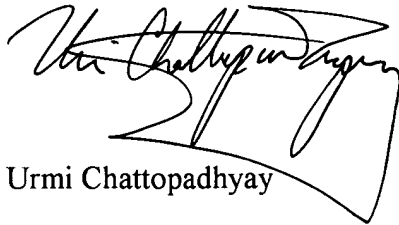
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Claim 9, see column 9, lines 28-33 for tubular sheath (138).

Claim 12, see column 7, lines 26-27 for catheter shaft positioned internal to the expandable conduit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.


Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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September 22, 2003



David J. Isabella
Primary Examiner